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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/678,490	10/03/2003	Derek Lydiate	11089.0003.NPUS01	8191
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HOWREY LLP-CA			ZHENG, LI	
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2941 FAIRVIEW PARK DRIVE, SUITE 200			PAPER NUMBER	
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			12/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/678,490

Applicant(s)

LYDIATE ET AL.

Examiner

LI ZHENG

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 1-8, 10 and 14 are pending and examined on the merits.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 30, 2009 has been entered.

Claims 1-8, 10 and 14 are pending and examined on the merits.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. The rejections and objection not set forth in this action are withdrawn.

Claim Rejections - 35 USC § 103

5. Claims 1-8, 10 and 14 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Fabijanski et al. in view of Mason et al. and Chou et al., for the reasons of record stated in the Office action mailed May 13, 2009. Applicants traverse in the paper filed September 11, 2009. Applicants' arguments have been fully considered but were not found persuasive.

Applicants argue that both construct in Fabijanski et al. encode a repressor and they both encode a lethal gene product (response, page 9, last paragraph). Applicants further argue that expression of the first nucleotide sequence containing the first coding region encoding a repressible tag protein is not benign to the plant, but instead results in a non-viable plant (response, page 10 3rd paragraph).

The Office contends that the instant claims do not exclude having a second repressor. The Office further contends that Fabijanski et al. teach a second nucleotide sequence comprising a new trait sequence (corresponding to a second regulatory region in operative association with a second coding region) and repressor 2 gene (corresponding to a third coding region encoding a repressor capable of binding to the operator sequence thereby inhibiting expression of the first coding region) (Figure 3). Further, although the Figure 3 of Fabijanski et al. teach lethal gene, according Example 5 of Fabijanski et al. the lethal genes includes conditional lethal gene such as oncogene 1 and 2 as a selection marker (Example 5, columns 33-35; also Table 1) which is similar to the conditionally lethal gene, *iaaH*, as disclosed in Example 5 of the instant specification. In addition, Fabijanski et al. teach that other conditionally lethal genes can also be used (the paragraph bridging columns 4-5 and column 5 lines 15-31).

Therefore, Fabijanski et al. teach a selection strategy that is benign and confers no adaptive advantage to the plant.

Applicants further argue that Fabijanski et al. do not disclose a plant selection strategy that is not based on antibiotic resistance because pCG-2 transformation vector includes a kanamycin resistance gene (response, page 12).

The Office contends that a plant selection strategy is interpreted as the one involved in the first, second and third coding region. Therefore the kanamycin resistance gene in pCG-2 used to introduce the first nucleotide sequence into plant is not considered as the plant selection strategy. Similarly, as shown in page 48-50 of the specification, the repressor gene is also introduced into the plant by using kanamycin resistance gene since p74-101 derived from pBI121 also contains a kanamycin resistance gene as a selection marker. Therefore, the method of Fabijanski et al. is not considered to be based on antibiotic resistance.

Double Patenting

6. Claims 1-10 and 14 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11 of US Patent Number 7,521,595 in view Mason et al. (1992, *PNAS* 89:11745-11749). Although the conflicting claims are not identical, they are not patentably distinct from each other because the US Patent Number 7,521,595 teach a transgenic plant comprising two constructs into a transgenic plant: a) a first construct comprising a first regulatory region operatively linked to a gene of interest and one or more Ros operator sequence; b) a second construct comprising a

second regulatory region operably linked to Ros repressor gene, wherein the gene of interest in the first construct comprises a conditional lethal gene, indole acetamide hydrolase, which is capable of being identified in a plant as a tag protein (page 20, lines 1-2).

The claim of US Patent Number 7,521,595 do not teach expression of another gene of interest or pharmaceutically active protein or any of the proteins listed in claim 10 in the second construct.

Mason et al. teach transgenic tobacco plants expressing the hepatitis B surface antigen under the control of CaMV 35S promoter (abstract; Figure 1).

It would have been obvious to add the expression cassette of Mason et al. to the second construct, resulting in the instantly claimed invention. One would have been motivated to do so given the teaching of Mason et al. that hepatitis B surface antigen could be used as a vaccine against hepatitis B virus infection.

Applicants traverse in the paper filed September 11, 2009. Applicants' arguments have been fully considered but were not found persuasive.

Applicants argue that in the construct of present invention, the gene of interest is located on the second construct whereas the construct of US Patent Number 7,521,595 contain gene of interest in the first construct (response, the paragraph bridging pages 15-16).

The Office contends that the gene of interest of US Patent Number 7,521,595 encodes tag gene of instant invention. Although the claim of US Patent Number 7,521,595 do not teach expression of another gene of interest or pharmaceutically

active protein or any of the proteins listed in claim 10 in the second construct, it would have been an obvious modification in view of Mason et al. as discussed above.

Summary

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Zheng whose telephone number is 571-272-8031. The examiner can normally be reached on Monday through Friday 9:00 AM - 5:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Li Zheng/
Examiner, Art Unit 1638